

REMARKS/ARGUMENTS

Claims 1-47 are pending. Claims 1-3, 6-9, 11, 13, 15-21, 23, 25, 27-32, 35, 36, 39-43, 45, and 47 were examined, with the remaining claims having been withdrawn pursuant to an election of species requirement. Claims 31-46 have been canceled without prejudice to refiling in a subsequent application. Reexamination and reconsideration of the claims are respectfully requested.

Claims 1-3, 6-9, 15-21, 27-32, and 39-43 were rejected as being anticipated by U.S. Patent No. 5,540,734 to Zabara and U.S. Patent No. 4,573,481 to Bullara. Such rejections are respectfully traversed.

As an initial matter, Applicants note that the Examiner appears to be combining the teachings of these two references. Thus, Applicants will assume that the rejection was meant to be stated under 35 USC § 103 for obviousness, not under § 102 for anticipation. It is noted, however, that neither of these references, taken alone or in combination, teaches each and every element of the independent claims of the present invention.

Independent claim 1 reads as follows:

"1. A method of disposing an activation device on a carotid sinus of a patient, the carotid sinus having a circumference, the method comprising the steps of:

providing an activation device having a base and a plurality of electrodes; and

positioning the device proximate the carotid sinus such that the base extends around at least a substantial portion of the circumference of the carotid sinus and the electrodes extend around the carotid sinus less than the base."

Claim 1 explicitly requires positioning an activation device "having a base and a plurality of electrodes" over a carotid sinus "such that the base extends around at least a substantial portion of the circumference of the carotid sinus and the electrodes extend around the carotid sinus less than the base." Such claim requirements are not taught by either Zabara '734 or Bullara '481.

As will be discussed more fully below, Zabara '734 does not in fact teach to one skilled in the art placement of an electrode structure of any sort around a carotid sinus. For present purposes, however, Applicants will note that the Zabara specification does state at Col. 4, lines 61-63, that "It may be convenient for a surgeon to locate an electrode at placement site 15 on the carotid sinus . . ." While placement site 15 is in fact on the carotid sinus nerve, even if one were to assume this taught placing an electrode on the carotid sinus, there is no remote teaching that the electrode comprise a base in a plurality of electrodes, much less that the electrodes extend around the carotid sinus less than the base."

Nor is this deficiency cured by the Bularra patent. Bularra teaches placement of electrode structures solely around nerves. While a particular electrode may include two electrodes 15a and 15b, there is no teaching or suggestion that placement of such a structure would ever be useful with a carotid sinus.

Nor would there be any motivation to combine the teachings of Bularra with those of Zabara. Even if Zabara is assumed to teach placement around the carotid sinus, the bifurcated structure of the carotid structure (which is illustrated at 14 in Fig. 2 of Zabara), seems incompatible with the helical structure of the electrodes of Bularra.

For these reasons, even if Zabara teaches placement of an electrode about the carotid sinus, the method of placement of independent claim 1 as well as claims 2-19 dependent thereon, would be neither taught nor obvious, even when combined with the teachings of Bularra.

Independent claim 20 reads as follows:

"20. (Previously presented) A method of disposing an activation device on a carotid sinus of a patient, the carotid sinus having a circumference, the method comprising the steps of:

providing an activation device having a base and a plurality of electrodes; and

positioning the device proximate the carotid sinus such that the electrodes are spaced about at least a portion of the circumference of the carotid sinus."

Claim 20 is similar to claim 1 in that it requires providing an activation device "having a base and a plurality of electrodes." Claim 20 differs from claim 1 in that it requires the

device to be positioned about a carotid sinus "such that the electrodes are spaced apart about at least a portion of the circumference of the carotid sinus."

For the reasons described above, even if Zabara is assumed to teach placement of "an electrode" about a carotid sinus, there is no teaching that the electrode comprise a base with a plurality of electrodes, nor that the electrodes be spaced about the carotid sinus. Zabara never shows anything other than a patch or a ring structure as an electrode. While Bularra does show electrode structures comprising a base with at least a pair of electrodes, there is no remote teaching or suggestion that they ever be placed around anything other than a nerve.

For these reasons, Applicants believe that the rejection of independent claim 20, as well as claims 21-30 dependent thereon are in condition for allowance.

Without conceding the correctness of the rejections, Applicants have canceled all device claims 30-46.

The sole remaining method claim is independent method claim 47 which reads as follows:

"47. (Currently amended) A method of disposing an activation device on a carotid sinus vascular wall of a patient, the carotid sinus vascular wall, the method comprising the steps of:

providing an activation device having a base and a plurality of electrodes; positioning the device proximate the carotid sinus; and suturing the base to the vascular wall."

Claim 47 has been rejected over Zabara and Bularra, as above, further in combination with Kieval '349. The Examiner argues that Zabara and Bularra teach all aspects of claim 47, except for the suturing step which is taught by Kieval. Applicants disagree with this assertion, and for the reasons set forth below traverse the Examiner's assertion that Zabara teaches placement of an electrode around the carotid sinus.

The most pertinent teaching in Zabara is found in Col. 4, beginning at line 45, which reads as follows:

"FIG. 2 illustrates possible sites for attachment of electrodes to the glossopharyngeal nerve. FIG. 2 shows schematically a generator 1, which may be surgically implanted at some point in the patient's body in a known manner. Preferably, the generator 1 is implanted in or near the chest. Extending from the generator 1 are one or more generator leads 2 which terminate at one or more electrodes, preferably helical electrodes, placed on the glossopharyngeal nerve 9. Recommended sites for electrode placement include site 10, which is where the glossopharyngeal nerve enters the brain through the jugular foramen 11. Alternatively or additionally, an electrode may be placed on the glossopharyngeal nerve at a point distal from the jugular foramen, as indicated, for example, by electrode placement site 12. One point distal from the jugular foramen is along the carotid sinus 13, which connects to the bifurcation of the carotid artery 14. It may be convenient for a surgeon to locate an electrode at placement site 15 on the carotid sinus, or an electrode placement site 10 just outside the jugular foramen, by first locating the bifurcation in the carotid artery 14, and tracing the glossopharyngeal nerve from that point."

While this passage includes the sentence that "it may be convenient for a surgeon to locate an electrode at placement site 15 on the carotid sinus . . .," reference to Fig. 2 clearly shows that placement site 15 is on the carotid sinus **nerve**, not the carotid sinus. As noted in the accompanying Declaration of Irving H. Zucker Ph.D., one skilled in the art would recognize that the structure labeled as 13 in Fig. 2, which extends between carotid artery bifurcation 14 and the glassopharengyl nerve 9 is the carotid sinus nerve, not the carotid sinus.

The fact that structure 13 in Fig. 2 is the carotid sinus nerve, not the carotid sinus, is supported by a later passage in the Zabara patent beginning at Col. 7, line 59, and reading as follows:

"After selecting the nerve which will receive the implant, one must determine the site at which the implant will be placed. As shown in FIG. 1, the trigeminal nerve has three nerve roots. An electrode may be placed at one or more of these roots. Alternatively, the electrode may be placed at the Gasserian Ganglion, which is a terminus for the three roots. Signals will travel from the Gasserian Ganglion to the Trigeminal Nucleus, and then generate impulses in pathways projecting to other areas of the brain. As shown in FIG. 2, the glossopharyngeal nerve may be accessed just prior to its entry into the brain, which occurs at the jugular foramen. Alternatively, one of the branches of the glossopharyngeal nerve may receive the electrode, including the carotid sinus nerve. The surgeon will often find it convenient to first locate the bifurcation of

the carotid artery, and at that point identify the carotid sinus nerve which may be traced to the jugular foramen."

With reference to Fig. 2, this paragraph clearly indicates that the electrode may be placed on the carotid sinus nerve, not the carotid sinus, and further that the carotid sinus nerve may be located by tracing between the bifurcation of the carotid artery and the jugular foramen. The structure between the bifurcation 14 and the jugular foramen 11 is clearly structure 13, which is indicated in this passage as being the "carotid sinus nerve."

For all of these reasons, it is clear, and would be clear to anyone of ordinary skill in the art, that the Zabara '734 patent does not teach placement of electrodes on the carotid sinus, but rather on the carotid sinus nerve, the glossopharyngeal nerve, or related nerve structures. As the Zabara patent is the only reference relied on by the Examiner as teaching placement of an electrode about the carotid sinus nerve, the rejection of claim 47, as well as all other method claims in the present application, must fail.

It is recognized by the Courts that anticipation cannot be supported by an error in the teachings of a prior art patent. See, *Edison Electric Light Company v. Novelty Incandescent Lamp Company*, 167 F. 977, 980 (3d Cir. 1909), where a patent relating to the structure of an incandescent light was asserted to be invalid over a drawing in an earlier patent. The court found, however, that the portion of the drawing which was being relied on was a mistake of the draftsman. There was no intent to show the novel structure. The court went on to find that in view of this clear error, no one reading the patent would understand the later novel idea of the second patent.

The present circumstances are equivalent to those faced in the court in *Edison*. As noted in the accompanying Declaration of Irving H. Zucker, Ph.D., one skilled in the art would realize that the assertion in Zabara that an electrode be placed around the "carotid sinus" was in error. Therefore one skilled in the art would not take away any teaching which would render the claimed placement of the electrode around the carotid sinus in the present application obvious.

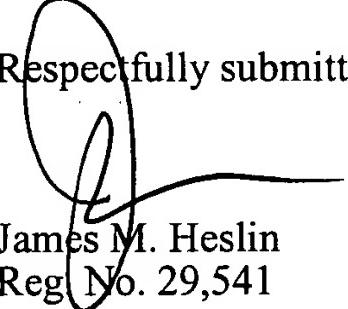
Appl. No. 09/963,777
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PATENT

In view of the above amendments and remarks, Applicants believe that all remaining claims are in condition for allowance and request that the application be passed to issue at an early date.

CONCLUSION

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at (650) 326-2400.

Respectfully submitted,

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